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| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/931,325 | BIRKETT, ASHLEY J. | |
| | Examiner Zachariah Lucas | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. This communication is responsive to the RCE of April 9, 2004, and paper of May 25, 2004.
- 2. The allowed claim(s) is/are 1,2,6-11,14-17,19,20,22-28,32-37,40-43,45,46,48,49,51,53,54,55-58,60-65,67,76 and 77.
- 3. The drawings filed on _____ are accepted by the Examiner.
- 4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of
 - Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
- 7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
 - Paper No./Mail Date _____.
- 4. Examiner's Comment Regarding Requirement for Deposit
 - of Biological Material
- 5. Notice of Informal Patent Application (PTO-152)
- 6. Interview Summary (PTO-413),
 - Paper No./Mail Date 5-25-2004.
- 7. Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 2 ,6-11,14-17,19, 20, 22-28, 32-37, 40-43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60-65, 67, 76, and 77 are pending and allowed.

2. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 9, 2004 has been entered.

3. Claims 1-11, 13-17, 19, 20, 22-30, 32-37, 39-43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60-65, and 67 were rejected in the prior action, mailed on October 20, 2003. In the Response filed on February 23, 2004 (and entered upon the filing of the RCE), the Applicant amended claims 1, 9, 14, 16, 23, 25, 27, 34-36, 42, 53, 56, 57, 58, 60, 61, and 63-65; and cancelled claims 3-5, 12, 13, 18, 21, 29-31, 38, 39, 50, 52, 55, 59, and 68-75. Applicant additionally added new claims 76 and 77; amended claim 40; and clarified the status of claims 44 and 47 in the Supplemental Amendment of May 25, 2004.

The claims have been amended such that they now read on chimeric HBc proteins comprising naturally occurring HBc protein sequence, wherein residues 1-149 of said sequence share at least 95% identity to the sequence identified as SEQ ID NO: 170, and wherein heterologous sequences have been inserted into said HBc sequence.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Edward P. Gamson on May 25, 2004.

The application has been amended as follows:

In **claim 1**, lines 6-11 (subpart (a)) of the claim have been deleted, and replaced with the following:

- - (a) Domain I comprises (i) the sequence from position 1 through position 75 of HBc, or (ii) a sequence of about 85 amino acids comprising a sequence heterologous to HBc peptide-bonded to one of the first five N-terminal residues of HBc, and including at least the sequence of the residues of position 5 through position 75 of HBc; - -

and, lines 12-14 of the claim (the first three lines of part (b)) have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 58 amino acid residues peptide-bonded to residue 75 of HBc, including (i) the sequence of positions 76 through 85 of HBc, and - - .

In **claim 9**, lines 8-10 (the first three lines of part (b)) of the claim have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 46 amino acid residues peptide-bonded to residue 75 of HBc, including (i) the sequence of positions 76 through 85 of HBc, and (ii) a sequence of 8 to about 36- - .

In **claim 27**, lines 7-12 (subpart (a)) of the claim have been deleted, and replaced with the following:

- - (a) Domain I comprises (i) the sequence from position 1 through position 75 of HBc, or (ii) a sequence of about 85 amino acids comprising a sequence heterologous to HBc peptide-bonded to one of the first five N-terminal residues of HBc, and including at least the sequence of the residues of position 5 through position 75 of HBc; - - .

and, lines 13-15 of the claim (the first three lines of part (b)) have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 58 amino acid residues peptide-bonded to residue 75 of HBc, including (i) the sequence of positions 76 through 85 of HBc, and - - .

In **claim 35**, lines 9-12 (the first four lines of part (b)) of the claim have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 46 amino acid residues peptide-bonded to residue 75 of HBC, including (i) the sequence of positions 76 through 85 of HBC, and (ii) a sequence of 8 to about 36 residues that - - .

In **claim 56**, lines 9-12 (the first four lines of part (b)) of the claim have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 46 amino acid residues peptide-bonded to residue 75 of HBC, including (i) the sequence of positions 76 through 85 of HBC, and (ii) a sequence that constitutes a B cell epitope- - .

In **claim 60**, lines 10-15 (subpart (a)) of the claim have been deleted, and replaced with the following:

- - (a) Domain I comprises (i) the sequence from position 1 through position 75 of HBC, or (ii) a sequence of about 85 amino acids comprising a sequence heterologous to HBC peptide-bonded to one of the first five N-terminal residues of HBC, and including at least the sequence of the residues of position 5 through position 75 of HBC; - - .

and, lines 16-18 of the claim (the first three lines of part (b)) have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 58 amino acid residues peptide-bonded to residue 75 of HBC, including (i) the sequence of positions 76 through 85 of HBC, and - - .

In **claim 61**, lines 9-12 (the first four lines of part (b)) of the claim have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 46 amino acid residues peptide-bonded to residue 75 of HBc, including (i) the sequence of positions 76 through 85 of HBc, and (ii) a sequence of 8 to about 36 residues that - -.

In **claim 62**, lines 3-5 of the claim have been deleted, and replaced with the following:

- - about 46 amino acid residues peptide-bonded to residue 75 of HBc, including (i) the sequence of positions 76 through 85 of HBc, and (ii) a sequence of 8 to about 36 - -.

In **claim 64**, lines 10-13 (the first four lines of part (b)) of the claim have been deleted, and replaced with the following:

- - (b) Domain II comprises about 18 to about 46 amino acid residues peptide-bonded to residue 75 of HBc, including (i) the sequence of positions 76 through 85 of HBc, and (ii) a sequence that constitutes a B cell epitope - -.

These amendments have been made to clarify the claim language.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 9-11, 13-17, 19, 20, 22-26, 35-37, 39-43, 45, 46, 48, 49, 51, 53, 54, and 56-58 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. These claims described a recombinant HBc protein wherein Domain III of the protein "consists essentially of the HBc sequence from position 86 through position 135" and Domain IV of the protein is peptide bonded to the residue at position 135, and Domain II comprises residues 76 to 85 of HBc. The claims were rejected as indefinite because it was not clear what is meant by the requirement that Domain III "consists essentially of the HBc sequence from position 86 through position 135." In view of the cancellation of the rejected language from the claims, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 9-11, 13-17, 19, 20, 22-26, 35-37, 39-43, 45, 46, 48, 49, 51, 53, 54, and 56-57 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were rejected because there was inadequate written description support for the language "consists essentially of" with reference to the constitution of Domain III. In view of the cancellation of this language from the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

7. **(Prior Rejection- Withdrawn)** Claims 1-4, 6, 7-11, 13-17, 19, 20, 22-30, 32-37, 39-43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60 and 67 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Pumpens (Intervirology 38:63-74) in view of Nardin PCT (WO 98/31382), Nardin (Science 246:1603-1606), Schödel (J. Exp. Med. 180:1037-1046), Bernardi (DE 3741183), Kratz (PNAS 96: 1915-1920), and Metzger (J. Gen. Virol., 79 :587-

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590). The rejected claims read on recombinant HBc chimeric proteins comprising a Plasmodium falciparum B-cell epitope (B epitope) between HBc residues 78 and 79, and optionally including a T-cell Plasmodium falciparum epitope (T epitope) at the C-terminus of the protein. The rejection was also extended to amended claims 61, 64, and 65. In the prior action, it was noted that the Applicant's arguments that the claimed invention, to the extent that it reads on HBc particles comprising the Plasmodium NANP repeat, provided unexpected results over those indicated in the prior art. In view of the amendment of the claims such that they read on only these embodiments, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 1-11, 16, 17, 19, 20, 22-30, 32-37, 42, 43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pumpens in view of Nardin PCT (WO 98/31382), Nardin (Science 246:1603-1606), Schödel, Bernardi, Kratz, and Metzger as applied to claim 1 above, and further in view of Colman et al., U.S. Patent 5,614,194 (of record in the IDS submitted on February 24, 2003). As was indicated in the prior action, this rejection was focused on the limitations of claim 5, which limited the inventions of claim 1 to embodiments wherein the Plasmodium is *P. vivax*. These embodiments have been cancelled from the application. In view of this, the rejection is withdrawn.

Conclusion

9. Claims 1, 2 ,6-11,14-17,19, 20, 22-28, 32-37, 40-43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60-65, 67, 76, and 77 are allowed.

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10. The following reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

U.S. Patent 6,231,864. This patent shares the same inventor and claims an invention generic to the presently claimed invention. However, while this patent appears to be a prima facie case for double patenting, it does not teach or provide any indication regarding the unexpected results argued by the applicant in the Response filed on July 15 2003, and discussed in the Office action mailed on October 10, 2003 in the present application.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


6/13/04
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